Part I – Introduction

Retired US Army Lieutenant General Rick Lynch, whose book, *Adapt or Die: Leadership Principles from an American General*, has inspired this Zensights meeting series, opened the evening by emphasizing the importance of building closer ties between the biopharmaceutical industry and the two federal government agencies responsible for 23 million veterans. “Today, less than one per cent of the US population has ever served in uniform and opinion polls show that three quarters of the public have little or no idea of what is going on with our veterans. This lack of awareness extends to business and industry as well, even though our veterans represent an untapped resource of experienced, productive human capital.”

In the biopharmaceutical field, the Veterans Administration [VA] and the Department of Defense [DOD] are deeply involved in issues of human health, with an unrivaled data base of billions of clinical interventions that spans decades and covers a range of conditions that coincides with many of the industry’s key priorities in R&D. “This is an area ripe for better collaboration and partnership,” Lynch said. “The theme for tonight is – so what can we do?”
Part II – Keynoter Summaries

Lynch was followed by the evening’s two lead speakers, VA Deputy Secretary Sloan Gibson, and Margaret “Peggy” Wilmoth, Deputy Surgeon-General of the US Army for Mobilization, Readiness and Army Reserve Affairs.

In his remarks, Gibson emphasized that, while the VA has extensive resources – the VA spends $5.5 billion on biopharmaceuticals annually along with an $1.8 billion budget for veteran’s health research – it cannot fulfill all its needs internally. He explained that VA Administrator Robert McDonald has made “strategic partnering” a top priority. “Bob and I are fellow West Point graduates who became friends on active duty, so we have approached our work at VA with a shared sense of humility – we don’t have it all figured out. It is important to learn from others, which is why our first goal was to create the extraordinary relationship we now have with DOD.”

Another aspect of the new leadership at VA is the commitment to a 21st century model of governance geared to practices that can be certified as “best in class” through quantitative, performance-based metrics. Management has cast the net widely, reaching out to other agencies in the federal government, the 50 states, the non-profit community, and business. An example of this modern, coordinated approach, Gibson said, is the Department’s all-out assault on veteran’s homelessness over the past year. “It’s a real best practice effort, with tangible results in terms of the number of vets we have brought back from the streets.” Gibson said more such public-private campaigns to tackle a specific challenge facing veterans will be rolled out over the next few months.
Why would the biopharmaceutical industry want to work with the VA? The answer, says Gibson, starts with scope, scale and reach – “the VA is involved at nearly every point of the delivery and financing chain for health care.”

Not only does the VA manage over 18,000 affiliations with health care institutions, ranging from rural hospitals and clinics to top academic teaching facilities, it contributes to training and instruction each year for 62,000 students in medical schools and 32,000 allied health professionals. If the VA operated as a for-profit business, it would rank in the Fortune 50, with 350,000 employees covering nine separate lines of business.

Another interesting statistic: VA runs what amounts to the 10th largest insurance enterprise in the US. Nine million veterans are currently receiving VA health benefits, with another six million enrolled in rehabilitation or disability care. VA facilities employ some 25,000 physicians, 90,000 nurses – the VA is the biggest employer of nurses in the US – and 8,500 pharmacists. Notes Gibson, “our health services are competent in every conceivable procedure, from primary chronic care to the most advanced organ transplants as well as everything in between. The VA mail order drug pharmacy has received the highest quality performance rating in the country from J.D. Powers.”

In addition, the VA has compiled a lengthy record of health innovations. The first successful liver transplant was performed at a VA hospital and the VA was an early adopter of the implantable cardiac pacemaker. VA-affiliated researchers are the recipients of three Nobel prizes on science and medicine. Other innovations associated with the VA include the development of the first prototype electronic health record [EHR]; the nicotine patch device; treatment
protocols for traumatic brain injury and injuries to the spinal cord; discovery of genetic risk factors for schizophrenia and Alzheimer’s; and advances in the technology for artificial limbs.

Gibson also pointed to the work VA is doing to leverage a rich trove of data from veteran’s health records, dating back to World War II. “We have a goal to collect the genetic profiles of one million of our veterans and pair it with our EHR to aid in medical research and related health applications,” Gibson said. The genetic record of 400,000 veterans has been loaded into the data base, so we are almost halfway to our goal. This one million veteran program will end up as a major contribution to medical research.” In addition, VA researchers have 13 study projects underway with the National Institutes of Health [NIH], covering key areas of interest to the Department like suicide prevention.

On pharmaceutical therapy and relations with the drug industry, Gibson referenced the VA’s success in providing 170,000 eligible veterans with hepatitis C access to a new generation of cures. “The VA has spent over $1 billion on these drugs, even before they were officially approved by the FDA. Last month, we launched a new plan to enroll another 1,900 patients per week on these cures, in cooperation with the drug manufacturers. The hepatitis C access initiative requires us to coordinate closely with industry in securing our objective – to make the federal budget system work for our patients.”

Gibson concluded by sharing a personal view on the factors that contribute to a successful collaboration. One of the most critical is acknowledging the possibility of conflict and to be open to seeking consensus in spite of variant interests, cultures and priorities. “If you approach a relationship solely on the basis of what’s in it for you, it
will not succeed. Partners have to be flexible; to adapt and bend toward something broader than that. In our case, the criteria is to be willing to think “out of the box” on what each partner can do to help our country deliver on its promises to veterans.”

He notes that this approach is not easy for any large government agency with a long history of relying on standardized protocols of behavior. “If there is one message I want to leave with you today it is that the VA is no longer wedded to the by-the-book philosophy of the past. The new VA is pushing to do many things that historically the internal culture here has resisted and not done. We want our external partners to nudge us to venture ‘outside the box.’ In fact, we want the same from you too – a fresh attitude toward new ideas can only be good for us.”

Margaret “Peggy” Wilmoth began her remarks with a description of Army Medical Department Corps [AMDC], a vast global network that provides a range of health services for 151,000 active duty and contract personnel located on five continents. The AMDC also conducts medical research; coordinates public health programs, including preventive and wellness initiatives; conducts research on health issues; and educates and trains health providers. In reference to the latter, the Army runs 148 graduate training programs and has its own annual R&D budget of $1.4 billion. Currently, there are four million people receiving Army health benefits; they and their dependents make 11 million outpatient visits annually.

“We are a world-class health provider as well as a continuous innovator dedicated to advances in disease prevention, wellness, and the treatment of combat casualties and related stress factors.” Wilmoth said. “Our mission is simple: to ensure our soldiers are combat ready and receive the best care for any injuries they
encounter in the service of our country.” The commitment even extends to a separate veterinary corps with a mandate to prevent the spread of animal-borne disease vectors posing a threat to humans.

Wilmoth described an important new emphasis for the Army on preventive health. “Rising health care costs for active duty personnel are eating away at the DOD budget. A force in uniform weighed down by high rates of diabetes, obesity and heart disease is not only less able to perform its combat mission, but the cost of care is diverting resources from other areas where we need to invest.”

The logical response, she said, is to educate the troops to make the case for their own health. “Our aim is to transition from a disease-centric model to one that emphasizes the whole person taking more responsibility to embrace individualized healthy behaviors like a low-fat diet, less alcohol, exercise and adequate sleep.” Wilmoth noted that it was not rhetoric that is driving AMDC to renounce use of the word ‘hospital’ in favor of ‘health readiness centers’ – it’s a good indication of where we are going.”

Part III - Panel Summary

Gibson and Wilmoth joined forces for a panel discussion, moderated by communications strategy consultant Chris Bowe, along with another expert guest, Harry Fisher, President of Health ResearchTx, whose company works with the DOD on projects that tap the DOD’s EHR system to conduct research studies, in collaboration with academia and private industry.

Fisher described work his firm did with the DOD and defense contractor Northrop-Grumman using EHR records to identify issues in drug adherence and compliance. “We were able to show from the
data that, while patients claimed to be compliant, the reality was often different. Records proved that many were taking 45 days or more to fill a 30-day prescription. Not taking the drug as prescribed at regular intervals prevents it from achieving the desired therapeutic effect, which harms patients and ends up costing the system money.”

Wilmoth pointed to a good example of an Army partnership – with GE, which provides training for army reservists in keeping them up to date on the latest technology and practice in information processing and data services.

Gibson raised the potential application of personalized medicine in VA programs, noting the VA has an unparalleled asset in the vast amount of data it has compiled over the year from patient records. At present, however, application of that storehouse to address veteran health challenges remains an aspirational goal. “It requires a clear estimation of what our capabilities are and the resources needed to answer such questions as how to sequence individualized data and render it so it can be accessible to the people practicing medicine. We are not there yet, which is why we would like to work with industry – to see how you are approaching this problem on your own home turf.”
Part IV – Building a Veteran’s Health and Research Agenda: Conclusions, Recommendations and Next Steps

Discussion then turned to the question posed at the outset of the evening by Lieutenant-General Lynch –
Where are the best potential areas of collaboration between government and industry?
What is the most productive path forward?

A synthesis of thoughts and recommendations from the full group discussion is as follows:

• The VA is interested in discussing ways to open its “million veteran” genetic profiling program to participation by biopharmaceutical industry companies, perhaps through sponsorship of joint areas of research investigating the genetic origins of selected diseases. Dr. Tim O’Leary, who leads the VA health research program, emphasized the potential savings on adverse effects and tolerability from the personalization of genetic data, allowing for greater precision in prescribing decisions, such as indicating the right statin for a patient, at the right dose. “What we aren’t able to do right now is take the raw data and turn it into something that can be applied directly to clinical decision-making. We’d like to talk to industry about that.”

• The VA and especially the DOD want guidance in pushing prevention/wellness programs to the next level, with messaging and incentive programs that induce individuals to make necessary behavioral changes on their own – and stick to them. “Adverse health impacts of tobacco, alcohol and obesity cost the DOD $2.4 billion a year in added health claims,” said Wilmoth. “It's low hanging fruit if we can shape the incidence of these three conditions – what are best practices we can apply from an industry that leads in persuading patients to take action to address a medical condition that many don't even know they have?”

• Industry participants responded by referencing examples of major disease awareness programs from Roche/Genentech on colon cancer screening, AstraZeneca on type 2 diabetes and healthy foods, Merck on vaccines compliance, Novo-Nordisk on helping pre-diabetics stay that way, and Biogen-Idec on managing MS. Industry participants agreed to funnel information on these programs to VA and DOD, with the appropriate company contacts.
• Lynch suggested a cooperative effort to identify areas of program/project overlap between the VA and DOD as well as gaps in resources and expertise. This work could be applied to clarify where the biopharmaceutical might be equipped to help.

• Fisher warned that collaboration involving government and industry requires due diligence to identify just where the interests of each party intersect – the match-up sequence is vital. “It starts with taking into account the long-term vs. short-term perspective. Government tends to think big and long, but a drug company is not going to be interested in the equivalent of a moon shot in health care. Projects involving the private-sector have to be carefully calibrated and defined,” Fisher said.

• Tim O’Leary said the VA recently held an open-house “genetics day” to brief and inform industry and other stakeholders about the million vet profiling work stream, which resulted in inquiries from 60 companies on ways to cooperate. The VA should consider applying this model to other areas of health research, research tools and policy.

• With that in mind, strong interest was expressed by both sides in the VA’s extensive research work on Post-Traumatic Stress Disorder [PTSD], where it has complied clinical data going back 50 years, to the Vietnam era. A number of drug companies are investigating compounds to treat PTSD, the incidence of which is also increasing in the general population. Sufficient interest was deemed to exist for a more formalized collaboration between VA and biopharma companies on sharing ideas and research, at the pre-competitive stage.

• Pain medication and opioid addiction is another research area of mutual interest.

• More should be done to increase visibility and access to the VA’s EHR data pool and to encourage its interoperability with data compiled among Army reservists who also receive care under private employer-based and other commercial plans. It was noted that the CMS has introduced an updated diagnosis and procedure coding system, ICD10, for health providers – is there a way to apply the new system toward a fully integrated approach? Without it, insights from the VA data could be lost on this wider population set.

• VA and DOD should jointly consider developing a protocol to facilitate contact and collaboration with smaller biopharmaceutical companies, as this would address the limited resources these companies have
to invest in external liaison-building. The therapeutic interests of smaller companies, which often make big bets in therapy segments that the big Pharma players ignore, also coincide with the two agencies’ commitment to basic research.

- ZenSight CEO Bob Jansen suggested a dedicated VA/DOD website as a “go to” destination for companies interested in hearing about, or working with, the two agencies on research or policy initiatives.

- In a more speculative vein, industry participants mused about amending FDA legislation to include incentives in the registration and approval process for compounds that address the special health needs of veterans and military personnel. One example cited is the FDA’s priority review voucher offered to drug candidates designed to combat the rising incidence of antibiotic-resistant bacterial infections. Information on these initiatives endorsed by Congress should be forwarded to Gibson, Wilmoth and their research staff for internal review.

- Lynch asked the two agency officials what the biopharma industry’s “army of lobbyists” could do to improve legislative prospects around their health and research agendas for veterans, reservists and active duty personnel. Wilmoth pointed to a need for the industry to extend its contacts beyond Ways & Means and Energy & Commerce to a more systematic outreach to committees like Armed Services and Veterans Affairs, each of which have members and staffers focused on veterans health policy and research issues.

- Another idea is to make the “health readiness” of the armed forces an agenda item on the periodic assessment of national security issues coordinated by congressional intelligence and foreign affairs committees and the White House.

Moderator Bowe and Zensights CEO Bob Jansen closed the meeting. It was agreed to have Lieutenant-General Lynch take conclusions from the meeting forward for a de-brief with veterans advocacy groups, including the Gary Sinise Foundation, as well as follow-up with Deputy VA Secretary Gibson, Deputy Surgeon-General Wilmoth, and their staffs.

*Meeting notes by W. Looney*

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